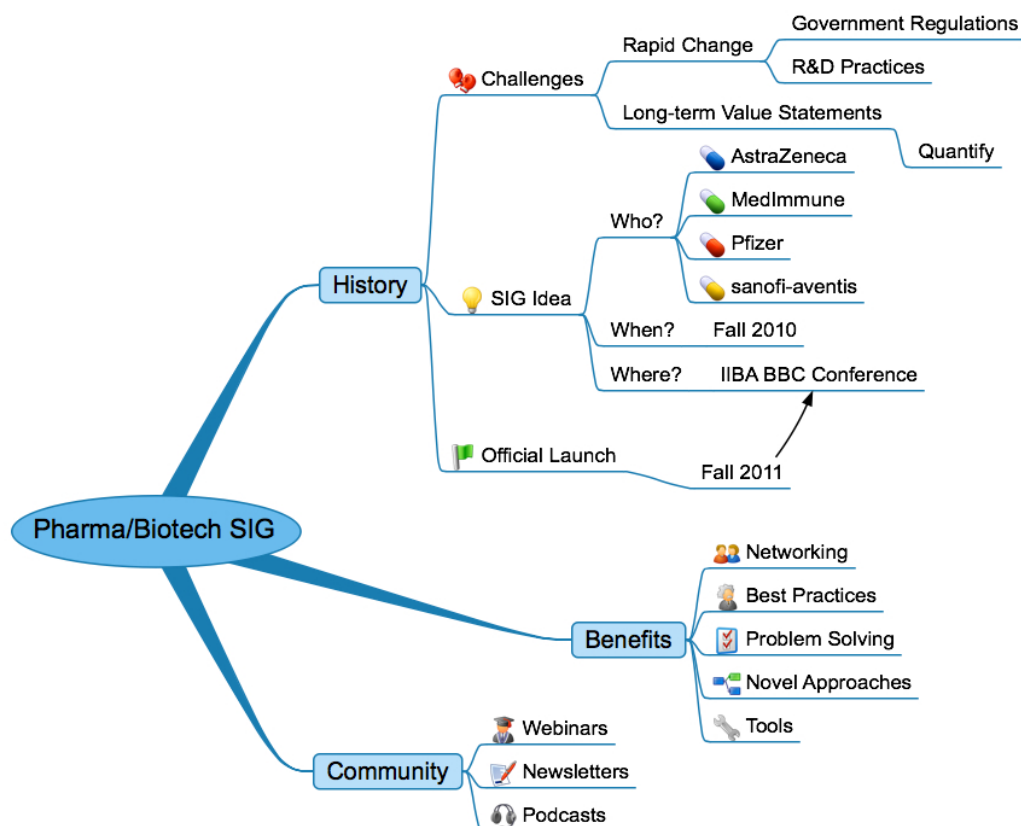


# HELIX

## The First Issue!

by David Benyon



As the editor, let me welcome you to the first issue of HELIX, the quarterly newsletter of the IIBA Pharma/Biotech Special Interest Group. Glad to have you as a reader, and hopefully as a future contributor.

If you are a member of the International Institute of Business Analysis (IIBA), you will have heard of the local chapters, where members in a particular geographical area can meet, learn and network. The Pharma/Biotech Special Interest Group is like a local chapter, except that we do our meeting, learning and networking online, and we focus on business analysis in the world of pharmaceuticals and biotechnology. Why is that?

The business world is in constant flux, and this is especially true in the pharmaceutical industry. Government regulations and R&D practices change rapidly, and a business analyst working in this field must have both the domain knowledge and technical skills to respond quickly. The article by Bill Nazzaro in this issue of Helix provides a good illustration of that.

Every year, the IIBA and others sponsor a week-long conference called Building Business Capability (BBC). It was at the 2010 event that some delegates from AstraZeneca, MedImmune, Pfizer and Sanofi had the idea of forming a group to serve the specific needs of business analysts in our domain. One year later, the Pharma/Biotech SIG was officially launched.

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## BA Conferences: Topics That Matter for Pharma/Biotech BAs

by Carol Scalice

Have you ever looked at those lengthy agendas for conferences and wondered if the high registration costs are worth it? Will they cover enough detail that I'll actually get something useful out of the talk? Will their examples be for such simplistic scenarios that I won't know how to apply that to my much more complex pharmaceutical or biotechnology project? With so many tracks, how do I know which topics will give me the best value for my time spent?

These questions and more float through my head as I see the almost daily onslaught of advertising emails from various conference providers in our field. Between the industry related conferences and the business analysis and IT conferences, there's so much to choose from! To top it off, shrinking training budgets make conferences an appealing choice because you can potentially use the time to learn a wider array of new things for the same amount of money as one targeted class. So how do I know if a conference is right for me, which one to pick and, once I'm there, which sessions are the best for me to attend?

Selecting the right conference should be based on your development plan and where you are trying to grow. In general, I recommend trying to balance industry related conferences and events with the business and IT conferences. Strong business domain experience is important for business analysts in Pharma/Biotech, so don't discredit those industry conferences when weighing your options. Not having a science background myself, I tend to prefer talks that specifically mention case studies or examples. Without extensive domain expertise, the theoretical talks can sometimes go right over my head and leave me feeling tired with little new knowledge gained.



When exploring business analysis or IT conferences, I like to review the agenda of topics before making my decision. Many conference providers offer much cheaper, discounted rates if you register before you even know who their speakers are. While that can be great for saving money, it is always a gamble on whether the topics they select will be the topics that are most important to you. The next thing I like to look at is the tracks and topics. If there are multiple tracks, but only one resonates with me, then I may find myself with sections of time that are essentially wasted because none of the topics are relevant for me. I prefer conferences where I have a hard time selecting between lots of great topics than following a single track through a dictated course.

Now that I've got my conference, how do I know which sessions to attend? As with all of these decisions, what is most valuable to you is a matter of personal discretion. If you are unsure, consult with your manager or a fellow business analyst for some ideas. When deciding amongst multiple sessions, I look at a combination of the presentation abstract and the speaker bio. Below are some factors I think about when selecting which sessions will matter most to me.

## Speakers

Because I work in pharmaceutical research, a speaker talking about applying business analysis to scientific areas is almost always top of my list. Be sure to think critically about the speaker's area of expertise. I've been to many talks by presenters in the insurance industry, for example, where business rules seem more straightforward and well defined. Business rules in the pharmaceutical domain are much more complicated, so it is difficult to apply what I've learned to my own situation. Think about the speaker's background and the topic. Do you think the conditions they are performing business analysis under are close enough to your own to learn from them? In addition, try to balance between speakers who are consultants and those who are practitioners. Consultants have a lot of expert knowledge to share, but practitioners are living and breathing many of the same challenges as you every day. Rounding out those viewpoints can give you a more holistic view on the discipline.

## My "Portfolio" of Topics

The second factor I consider when assessing topics is kind of like balancing my learning portfolio, so to speak. I try to find a balance of techniques that I am unfamiliar with and those that I already know. The completely unfamiliar techniques give me exposure to a new concept that I could potentially apply on a current project or on something different in the future. Talks on the topics I already know can help me see how others are doing similar work and if there are tips or tricks that I could apply to my own practices. It is important to continually refine and sharpen the skills you already have.

## Applicability

In general, you learn more by applying new skills and techniques quickly. Look for topic areas that you think you can apply to work you are already doing or will be doing within the next few weeks. For example, the word "process" tends to scare many research scientists. Unless I am working on a process analysis/redesign project, I may not spend as much time on those courses. Alternatively, I may spend more time in sessions that

focus on common topics for pharmaceutical research, such as data analysis, user acceptance, or lean or agile business analysis. BAs on large, validated projects in a Development or Medical type of space, for example, may focus more on topics such as business rules, requirements management practices, risk analysis, process analysis. I encourage you to think about which topics would more commonly apply to the area you work in and that you would have a greater opportunity to apply in your day-to-day work.

## Format

When reading the abstract for the presentation, look for speakers who mention opportunities for discussion or interactivity in their sessions. These sessions can be great ways to break up the monotony of a long conference and help solidify learning. Activities and discussion groups can help you apply what you learn in the session and ask clarifying questions that help tailor the learning. At many conferences, the more interactive sessions are held as workshops on days before or after the core conference. I suggest looking for sessions that give you an opportunity to interact not only with the speaker, but also with other business analysis practitioners who can help you by learning from one another.

Choosing the right conference and the right talks within that conference can be a challenging task. In this article I've talked about a number of considerations that I think about when making the decision. These factors are just a few that matter to me. As a business analyst, I encourage you to think about your "requirements" for the conference. What would you like to get out of it? What are your learning goals? Can this person help me meet my learning objective on this topic? Do I think they have some value to add for my industry and how I'm trying to apply these skills? I like to think of it as decision analysis for the analyst. Yet another opportunity to apply those BA skills to solve real-world problems!



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## The Business Analysis of Life

by Matt St Louis

Not that long ago, on a typical day, the realization hit me... I was going to be 40 soon. I did not fear it. I did not dread it. I just felt like I needed to do something. Is that what a mid-life crisis is? Who knows? All I can tell you is that I needed to do something. But what? Being the shy, introverted guy that I am, I decided I needed to break the mold and do something, well...a little on the edge. And there was the first step in my quest (the first step in business analysis). My business objective was to increase my street cred with my loved ones, the cool kids in the office, and myself!

So, with my business objective in place, it was time to do some stakeholder analysis. My list of stakeholders and what was important to each can be summarized as follows. I'll start with my three children, the first two are three years apart and the youngest is three and a half years after the second. My oldest just finished his sophomore year of college, so I am two years into an 11 year stretch of paying college tuitions. I also really enjoy doing anything active with them. There is my girlfriend, x number of years my junior and extremely active (running, horseback riding, etc.). She can add humor to almost any situation and lives life to its fullest. I do my best to keep up with her. I work in an open environment and am very lucky to sit among some great people, I'll call them the cool kids. From the teasing and taunting (all in good fun), stories from 5Ks, half and full marathons, trail runs, or just what happened over the weekend or at bowling last night, I couldn't ask for better co-workers.

I kept the enterprise analysis short and sweet, I had only my disposable income and free time available. Both of those were limited, but I was willing to allocate from those as needed. I determined that some level of risk was required to truly accomplish my goal, but that level would have to be managed according to the environmental controls (refer back to sentence 1 of this article). I looked in the mirror and presented my business case. The story could have ended here, but fortunately the voices in my head approved the project and so I proceeded to requirements elicitation. I decided to conduct a self-brainstorming session. My requirements were simple... Do something that many would not. Do something that involves some chance of death. Do something that could be captured for posterity. I also conducted interviews with a few of my key stakeholders.



At this point, I reflected. I had my business objective, I had conducted my stakeholder analysis, I have elicited my requirements. With all of that in hand (or in mind), I assessed my potential solutions.

Option one: I could get a tattoo. This failed to meet my requirements as there was little chance of death and more and more people are getting inked these days.

Option two: climb into the octagon (that's compete in a Mixed Martial Arts match for those new to the program). This option met all of my requirements, but failed my stakeholder analysis and constraints (having not trained in about 5 years, needing to lose about 35 pounds to get to a competitive weight, having 9 years of college tuition payments left, wanting to still have all arms and legs in place to play tennis with my daughter or baseball with my sons, etc.).

So option three was the selected solution! I would undertake the Tough Mudder at Mount Snow in Vermont. The Tough Mudder, dubbed "Probably the Toughest Event on the Planet" is a series of 10-12 mile obstacle courses that feature 25-30 military style obstacles.

With my solution selected, I proceeded to the training and support requirements. Training would need to involve a significant amount of running and weight training to prepare for the distance of the course and difficulty of the obstacles. In terms of support, my girlfriend not only trained with me, but also decided to undertake the challenge as well.

Solution validation! At 3:30 am on Saturday, May 5, 2012, my alarm went off. I got out of bed, showered, ate breakfast and we departed for Vermont. As our 8:40 am start time approached, we moved towards the starting line, recited the Tough Mudder pledge, counted down from 10 and began what would be the most physically draining experience of my life to date.

The running helped with the overall distance of the course and to some degree with the endless hills. The weight training helped with some of the obstacles, like climbing over series of 8 foot (and later 12 foot) Berlin walls, carrying a log up and down the mountain, or crossing a set of monkey bars.

But it was the mental preparation and fortitude that was required the most. Willingly jumping into a

dumpster, not an empty dumpster or a dumpster of trash, but a dumpster that was full. Full with 30% colored water and 70% ice cubes. Going up and down a mountain, dozens of times. Making your way through mud, crawling in mud and rocks under barbed wire and through dark tunnels up the mountain side, spending several minutes crossing 39 degree water, running through fire.

And finally, with the finish line just a measly 100 feet away, five hours after beginning this quest, and having just managed to run and climb up a 16 foot high quarter pipe that was covered in mud and a few patches of blood from fellow Mudders, just one obstacle stood between us and the finish line. Would the legs hold up? Would the mind allow for the final challenge? We had to hurdle a series of hay bales, harmless enough, except for the field of hanging wires from above. Many of which were live, some carrying charges of 10,000 volts.

The course issued its final challenge as I hurdled the final bale, a live wire wrapped around my neck, issuing a series of zaps for what felt like a minute, but was actually more like a single second. And with that, I took the final few steps and received my coveted orange headband. Solution validated!

For more information on the Tough Mudder, visit [www.toughmudder.com](http://www.toughmudder.com)



Photo courtesy of Dmitry Gudkov ([www.gudphoto.com](http://www.gudphoto.com))



## New Legislation Results in New Business Requirements

by Bill Nazzaro



As a business analyst, new laws and regulations can trigger a need from your stakeholders. Dealing with anything truly new requires a different level of focus on requirements, and interactions with unexpected stakeholders. There may not be subject matter experts on a new law or regulation, and approaches that work for one piece of the business may not work for your solution. Keeping up to date on changes, new information, and proposed solutions is imperative to a successful project.

The U.S. Supreme Court recently ruled on President Obama's Patient Protection and Affordable Care Act, upholding major portions of the law. Part of the new law requires payment transparency, known as the Physician Payments Sunshine provisions. This requires manufacturers of drugs, biologics and medical devices to report annually to the Department of Health and Human Services of the federal government on their payments and other "transfers of value" to recipients covered by the law, which includes physicians and teaching hospitals. As a business analyst at a healthcare company running clinical trials, I am working on a project implementing a system to capture data on payments for clinical trials.

This project began as a process improvement / system upgrade. The prior system used to track payments was not designed for life sciences or clinical trials; it was a project management system. It could track how many nails were purchased for a

construction site, and the clinical payments department had to customize it to work for clinical trials. In a trial (or study), the work is done at a doctor's office or hospital. The study subjects are seen and study drug is administered by a healthcare provider running the study. Data is collected according to the trial protocol, and the healthcare provider is paid for their time, as well as for facility and staff time.

After determining that we wanted to replace the current system with one designed for clinical trials, this project was added to the company-wide program tasked with compliance of the new law.

I won't get into the specifics of user requirements, vendor selection, and marrying our requirements with the selected system's functionality, as this is similar in any project implementing a new system. What makes this project different is the influence of two important stakeholders: the systems we interfaced with and the law itself.

One thing that was very different is that the law is new. I have worked with regulations in the past (21 CFR Part 11 is a familiar regulation in clinical system development), but there is a lot of history and training available in implementing those. With a new law, I wanted to read the portion of both the law and the draft regulations issued by the government that directly impacted my system. The project team had to make decisions without much history and common practice to guide us. We report clinical spend to Vermont, but I have not been involved with that process; this was all new to me. I felt the better my understanding of what was required, the better I could interact with our stakeholders in legal, compliance and clinical.

I wanted to ensure I had a sense of what was required and why. Although our legal and compliance departments were involved in the project, I wanted to know the full picture of where our requirements came from. I needed to have it all in my mind of how the parts fit together. Just like sitting with an SME to see how they do their job and why they make decisions to better understand their process to determine areas for improvement, I spent time with the law and draft regulations so I could understand what was required from my company to the government.

The other major challenge was dealing with a vendor trying to interface multiple systems with data from different sources. This is where working with clinical trials makes things more interesting. A speaking event generally occurs in one day, and the information related to the event can be reported in a short amount of time. A clinical trial can run over years. Even a six-month trial will most likely run over two calendar years; and the reporting is to be on an annual, calendar-year basis.

So we needed to educate the vendor about the differences presented by clinical trials.

- What is the location of a clinical trial with 35 sites across the U.S.?
- What is the start date when each of those sites sees patients at different times, with 18 visits scheduled for each patient?
- How do we handle data exceptions, and is it different from the other systems?

These challenges are not that different from any other project you might have as a business analyst; each project is unique in its own way. We need to recognize that solutions are rarely simple; if they were, we wouldn't be involved.

It's navigating the differences that make my job interesting, moving from one project to the next. The questions are often the same ("what do you need?"), but the answers vary widely.

The new system is now in production. It is tracking payments, and hopefully, when we need to use the collected data to report, all of my work will pay off.



## Would Your Company Like to S----- Us?

by Leah Estberg

Say what? We are reluctant to use the "S" word, because you will think we are looking for money. Looking to part you from your cash. Nothing could be further from the truth.

The "S" we are looking for has nothing to do with money, but it has everything to do with encouraging the business analysts in your organization to join our group, share their knowledge with us, and let us share our knowledge with them. It is a win-win for everyone, and it will not cost a dime.

The "S" we are looking for is Sponsorship. Here's how you can help your business analysts develop their expertise by joining the only group in the International Institute of Business Analysis focused on the Pharma/Biotech business domain. And did we say it was free?

The Pharma/Biotech SIG is part of the International Institute of Business Analysis (IIBA). The IIBA is a non-profit professional association with a mission to develop and maintain standards for the practice of business analysis.

Launched in October 2003, the IIBA has:

- over 25,000 individual members.
- 130 corporate members worldwide.
- 4 webinars per month with on average 300 attending each webinar.

The Pharma/Biotech SIG also hosts webinars and over 400 attended the June webinar!

So that's who we are, and we want you on board. Just think of the benefits!

- Your business analysts engaged in learning and knowledge sharing with others in the field.
- Your company's name and logo displayed in our publications and webinars.

If you are interested to learn more, please contact Leah Estberg VP of Sponsorship, IIBA® Pharma/Biotech Special Interest Group

([Innovation@CadenceDynamics.com](mailto:Innovation@CadenceDynamics.com)). 



*Continued from Page 1*

First, we offer a community of like-minded professionals with a broad range of experience in the Pharma/Biotech domain. We have a LinkedIn page, where you can both ask and answer questions, or add to a particular discussion thread.


Second, we organize monthly webinars on topics ranging from the work of the Pistoia Alliance on pre-competitive collaboration, to the application of Lean Six Sigma.

Third, we have launched a podcast, which is hosted at [www.bareflections.com](http://www.bareflections.com). Check out the interview with SIG President Carol Scalice, who talks about how she became a BA, and offers some helpful advice to analysts looking to enter the field.

Fourth, you are reading the first issue of Helix, the newsletter of the Pharma/Biotech SIG. With your contributions, this newsletter will continue to publish news and articles specific to business analysis in the Pharma/Biotech domain.

Whether you want to contribute to our discussion group, present or attend a webinar, record a podcast with me, or submit an article to this newsletter, WE WANT TO HEAR FROM YOU!

The members of our board are listed on the right, so please feel free to contact us.

Thanks again for reading Helix! 

## Calendar

### September 24, 2012

Webinar: Support for Pharma Sales and Marketing

Presenter: Kathy O'Brian, Merck

### October, 2012

Webinar: How I Became a BA

Presenter: Panel of BAs

### October 28 - November 1, 2012

Building Business Capability (BBC) Conference

Westin Diplomat Resort and Spa

Fort Lauderdale, Florida

### November 14, 2012

Webinar: Understanding Your Communication Style and Maximizing Collaborative Interactions

Presenter: John Kuchna, President of Strategic Outcomes

## Meet Your Board Members



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